REMARKS

Claims 1, 7, 9-11, 16-17 and 20-28 were pending in the subject application. In this amendment claims 1 and 16 have been amended, claim 7 has been cancelled, and new claims 79 and 80 have been added. Claims 1, 9-11, 16-17, 20-28, and 79-80 are now pending in the subject application.

Claim 1 has been amended to specify that the azithromycin form conversion stabilizing excipient "is a surface tension reducing excipient." Claim 1 has also been amended to specify that "said surface tension reducing excipient is present in said powder for oral suspension in an amount sufficient to provide a surface tension of less than about 50 dynes/cm when an amount of said powder for oral suspension containing about 1 g of said non-dihydrate azithromycin is reconstituted with 10 ml of water." Claim 1 has also been amended to delete the term "and" after the first recitation of the term "non-dihydrate azithromycin."

Claim 16 has been amended to replace the phrase "form conversion stabilizing excipient" with the phrase "surface tension reducing excipient."

New claim 79 depends upon claim 9 and specifies that the azithromycin surface tension reducing excipient is an anionic surfactant.

New claim 80 depends upon new claim 79 and specifies that the anionic surfactant is selected from the group consisting of sodium lauryl sulfate and sodium dioctyl sulfosuccinate.

Support for the amendment to claim 1 can be found in the original specification at, for example, original claim 7; page 11, lines 30-32; page 13, lines 11-16 and 17-21; and Example 4, pages 43-46.

Support for the amendment to claim 16 can be found in the original specification at, for example, page 11, line 23.

Support for new claims 79 and 80 can be found in the original specification at, for example, page 11, line 25; and page 12, lines 3-4.

No new matter has been added, and entry of this amendment and reconsideration of the pending claims are respectfully requested.

I. Obviousness-Type Double Patenting Rejections of Claims 1, 7, 9-11, 16-17 and 20-28

The Examiner has maintained her rejection of claims 1, 7, 9-11, 16-17 and 20-28 on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent No. 6,861,413 ("the '413 patent"). The Examiner has maintained her rejections of claims 1, 7, 9-10, 16-17, 23 and 26 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3 and 4 of co-pending Application No. 10/355,575 ("the '575 application"). The Examiner has maintained her provisional rejection of claims 1, 7, 9-10, 16-17, 20, 23 and 26 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 15-37 of co-pending Application No. 10/327,383 ("the "383 application").

As a preliminary matter, claim 7 has been cancelled thereby rendering the Examiner's rejection of that claim as moot.

As noted in the amendment filed on June 28, 2007, Applicants will address the obviousness-type double patenting issues once the claims of the subject application are otherwise in condition for allowance.

II. **Rejection of Claims 1, 7, 9, 10, 16 and 17 under 35 U.S.C. § 102(b)**

Claims 1, 7, 9, 10, 16 and 17 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 679,400 ("Curatolo") for the reasons set forth in the office action. In particular, the Examiner states that "Curatolo et al. teach a powder for oral suspension containing azithromycin, flavorants (e.g., vanilla, banana, etc.) and wetting agents such as sorbitan monolaurate and polysorbate 80. See p. 7, lines 20-37. The powder of Curatolo et al. may also contain artificial sweeteners. See p. 7, lines 20-21." The Examiner further states that "[t]he azithromycin of Curatolo et al. includes the pharmaceutically acceptable salts thereof, as well as *anhydrous* and hydrated forms. See p. 4, lines 39-40." (Emphasis in original.) The Examiner still further states that "[t]he teaching of the 'anhydrous' form of azithromycin anticipates the claimed limitation 'non-dihydrated azithromycin.' The flavorants of Curatolo et al. anticipate the claimed limitation 'an azithromycin form conversion enhancer,' the wetting agents of Curatolo et al. anticipates the claimed limitation 'an azithromycin form conversion stabilizing excipient.'" Applicants traverse this rejection.

As a preliminary matter, claim 7 has been cancelled, thereby rendering moot the Examiner's rejection of that claim.

As discussed in the Amendment filed on June 28, 2007, Curatolo relates to a method of oral administration of azithromycin which does not exhibit an adverse food effect. Curatolo describes a powder used to make a suspension which "may also contain optional ingredients such as" wetting agents, anti-foaming agents, sweeteners and a buffer (see page 7, lines 2-5 of Curatolo). However, Curatolo does not disclose or describe a powder containing a surface tension reducing excipient wherein "said surface tension reducing excipient is present in said powder for oral suspension in an amount sufficient to provide a surface tension of less than about 50 dynes/cm when an amount of said powder for oral suspension containing about 1 g of said non-dihydrate azithromycin is reconstituted with 10 ml of water." Therefore, amended claim 1 is not anticipated by Curatolo for at least this reason, too.

Claims 9, 10, 16 and 17 depend directly or indirectly upon claim 1. Thus, these claims are also not anticipated by Curatolo for reasons set forth above.

In view of the above, Applicants respectfully submit that claims 1, 9, 10, 16 and 17 (claim 7 having been cancelled) are not anticipated by Curatolo, and request that the rejection of pending claims 1, 9, 10, 16 and 17 under 35 U.S.C § 102(b) be withdrawn.

III. **Rejection of Claims 1, 7, 9, 10, 16, 17, 20, 21, 23, and 24 under 35 U.S.C. § 102(e)**

The Examiner has rejected claims 1, 7, 9, 10, 16, 17, 20, 21, 23, and 24 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,764,997 to Tenengauzer et al. ("Tenengauzer") for the reasons set forth in the office action. In particular, the Examiner states that "Tenengauzer et al. teach stabilized azithromycin dosage forms, including powders to make oral

suspension, comprising flavorants such as vanilla, grape and banana ('an azithromycin form conversion enhancer') of the instant claims), wetting agents such as sorbitan monolaurate and polysorbate 80 ('an azithromycin form conversion stabilizing excipient' of the instant claims), and sweeteners. See col. 5, lines 9-24; col. 6, lines 32-60." The Examiner further states that "Tenengauzer et al. teach azithromycin ethanolate monohydrate (form F) as the preferred azithromycin form. See col. 3, lines 1-6." The Examiner asserts that "Tenengauzer et al. teach each and every limitation of claims 1, 7, 9, 10, 16, 17, 20, 21, 23 and 24. Applicants respectfully traverse.

As a preliminary matter, claim 7 has been cancelled thereby rendering moot the Examiner's rejection of that claim.

Tenengauzer relates to azithromycin dosage forms which include a stabilizing effective amount of an anti-oxidant (see col. 1, lines 61-77). However, Tenengauzer does not disclose or describe a powder containing a surface tension reducing excipient wherein "said surface tension reducing excipient is present in said powder for oral suspension in an amount sufficient to provide a surface tension of less than about 50 dynes/cm when an amount of said powder for oral suspension containing about 1 g of said non-dihydrate azithromycin is reconstituted with 10 ml of water" as recited in amended claim 1. Therefore, amended claim 1 is not anticipated by Tenengauzer for at least this reason, too.

Pending claims 9, 10, 16, 17, 20, 21, 23 and 24 depend directly or indirectly upon amended claim 1. Thus, these claims are also not anticipated by Tenengauzer for the same reasons as set forth above.

In view of the above, Applicants respectfully submit that claims 1, 9, 10, 16, 17, 20, 21, 23 and 24 (claim 7 having been cancelled) are not anticipated by Tenengauzer, and request that the rejection of pending claims 1, 9, 10, 16, 17, 20, 21, 23 and 24 under 35 U.S.C § 102(e) be withdrawn.

IV. Rejection of Claims 11 and 20-28 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 11 and 20-28 under 35 U. S. C § 103(a) based on a combination of Curatolo with the references discussed in detail below. We traverse the Examiner's rejection for the reasons discussed below.

Amended claim 1 of the subject application is directed to a powder for oral suspension comprising a non-dihydrate azithromycin; an azithromycin form conversion stabilizing excipient which is a surface tension reducing excipient; and an azithromycin form conversion enhancer. Amended claim 1 also specifies that "said surface tension reducing excipient is present in said powder for oral suspension in an amount sufficient to provide a surface tension of less than about 50 dynes/cm when an amount of said powder for oral suspension containing about 1 g of said non-dihydrate azithromycin is reconstituted with 10 ml of water." As explained by Applicants, the conversion of the non-dihydrate form of azithromycin into another form occurs more readily when the powder contains certain form conversion enhancers such as, e.g., flavors and a volatile organic component (see p. 1, line 32 to page 2, line 3 of the application). As also noted by Applicants, "[c]onversion from one form of azithromycin to another is undesirable as the subsequent azithromycin forms may not be bioequivalent to the initial azithromycin form. This potential change in bioequivalence, due to

azithromycin form conversion, could result in administering an underdose or overdose of azithromycin to a patient, which is particularly significant for pediatric patients who require tighter dosing regimens" (see page 2, lines 5-12 of the application).

Applicants found that the conversion of non-dihydrate forms of azithromycin into some other form can be minimized if a sufficient quantity of a suitable conversion stabilizing excipient which is a surface tensioning agent is present in the powder for oral suspension. As shown in Example 4 (Tables 4 and 5), reduction of the surface tension of the below about 50 dyne/cm reduces the extent of azithromycin form conversion compared to a control sample which does not contain any surface tensioning agent. Such stabilization of non-dihydrate azithromycin using a conversion stabilizing excipient which is a surface tensioning agent is neither taught nor suggested in any of the cited references.

"Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art" (see MPEP 2144.08.B).

None of the combination of references cited by the Examiner (and discussed below) teaches or suggests a powder for oral suspension containing the recited amount of surface tension reducing excipient; and none of the combination of references cited by the Examiner teaches or suggests the unexpectedly improved stabilities of the claimed formulations.

1. Rejection of Claims 20, 21, 23 and 24 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 20-21 and 23-24 under 35 U. S. C § 103(a) as allegedly being obvious over Curatolo in view of either Tenengauzer or U.S. Patent No. 6,977,243 to Li et al. ("Li") for the reasons set forth in the office action. The Examiner concedes that Curatolo "does not explicitly teach the claimed forms of azithromycin. However, Tenengauzer et al. teach using azithromycin ethanoloate monohydrate (form F) in stabilized powders for oral suspensions as discussed above." The Examiner further states that "[a]lternatively, Li et al. teach using the azithromycin forms of the instant claims in pharmaceutical compositions, including powders for oral suspensions. See col. 2-4; col. 26, lines 35-36." The Examiner still further states that "[t]he crystal forms of azithromycin show improved stability as compared to form A. See col. 14, lines 40-50." The Examiner contends that "it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanolate monohydrate or other non-hydrate crystal forms of azithromycin instead of anhydrous azithromycin." The Examiner asserts that "[o]ne having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by either Tenengauzer et al. or Li et al." Applicants traverse.

a. **Claims 20-21 and 23-24 are not obvious over Curatolo further in view of Tenengauzer**

Curatolo describes an azithromycin-containing powder used to make a suspension that "may" contain "wetting agents including, e.g., sodium lauryl sulfate (see page 7, lines 2-3). However, nowhere does Curatolo teach or suggest including a "wetting agent" in an amount sufficient to produce the surface tension for a powder such as that recited in amended claim 1. In fact, Curatolo's

only description for the amount of sodium lauryl sulfate is in the context of a lubricant for a **tablet formulation** (from "0.5% to 7.0% of the total **tablet weight**" (see page col. 6, lines 11-13) (emphasis added). In contrast, the claims of the subject application are directed to *powders* for oral suspension. Thus, there is no teaching or suggestion in Curatolo to make or use a powder having the amount of surface tension reducing excipient recited in amended claim 1.

With regard to Tenengauzer, Applicants submit that Tenengauzer provides boiler plate descriptions of ingredients that "typically" are present or "may" be present in his formulation. Nowhere does Tenengauzer direct one of skill in the art to make or use a composition comprising azithromycin, a flavor (conversion form enhancer) and a wetting agent (conversion form stabilizing excipient which is a surface tension reducing excipient). Tenengauzer states the his powder "may" contain "agents such as sorbitan monolaurate, polysorbate 80, and sodium lauryl sulfate" (see col. 6, lines 54-57). However, nowhere does Tenengauzer teach or suggest including an amount of "wetting agent" in an amount sufficient to produce the surface tension in amended claim 1. In fact, Tenengauzer's only description on the amount of sodium lauryl sulfate to use is in the context of a **tablet formulation** (see Examples 3 and 4). In contrast, the claims of the subject application are directed to *powders* for oral suspension. Thus, there is no teaching or suggestion in Tenengauzer to make or use a powder having the amount of surface tension reducing excipient recited in amended claim 1.

In summary, the combination of Curatolo and Tenengauzer does not teach or suggest modifying the powders described in Curatolo to include the amount of surface tension reducing excipient of the powders for oral suspension recited in amended claim 1.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 (CCPA 1974)).

In summary, Curatolo in view of Tenengauzer does not teach or suggest making or using any powder having the amount of surface tension reducing excipient recited in amended claim 1. Moreover, Curatolo in view of Tenengauzer does not teach or suggest the unexpected improvement in stability exhibited by the powder recited in amended claim 1. Thus, amended claim 1 of the subject application is not obvious over Curatolo in view of Tenengauzer for at least these reasons. Therefore, claims 20-21 and 23-24, which depend directly or indirectly upon amended claim 1, are not obvious over Curatolo in view Tenengauzer for at least these reasons, too.

b. **Claims 20-21 and 23-24 are not obvious over Curato further in view of Li**

As explained above, there is no teaching or suggestion in Curatolo to make or use a powder having the amount of surface tension reducing excipient recited in amended claim 1. Li relates to crystal forms of azithromycin. Li describes a number of routes of administration of his crystal forms, one of which is "oral suspension" (see col. 26, lines 24-37). Li does not describe any powder formulations containing a surface tension reducing excipient (e.g., a surfactant). Instead, Li's only disclosure of sodium lauryl sulfate (a surface tension reducing excipient) is in the context of a **tablet formulation** (see Example 14, col. 22; and col. 26, lines 51-53).

In summary, Li provides no teaching or suggestion to modify the disclosed powder formulation of Curatolo to contain a surface tension reducing excipient in the amount recited in amended claim 1. Moreover, Curatolo in view of Li does not teach or suggest the unexpected improvement in stability exhibited by the powder recited in amended claim 1. Thus, claims 20-21 and 23-24, which depend directly or indirectly upon amended claim 1, are not obvious over Curatolo in view Li for at least this reason.

In view of the above, Applicants respectfully submit that claims 20, 21, 23 and 24 are not obvious over Curatolo in view of either Tenengauzer or Li, and request that the rejection of claims 20, 21, 23 and 24 under 35 U.S.C § 103(a) be withdrawn.

2. **Rejection of Claims 21 and 22 under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 21 and 22 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of either Tenengauzer or Li, and further in view of WO 2004/000865 ("Schwarz") for the reasons set forth in the office action. In particular, the Examiner concedes that "Curatolo et al. does not explicitly teach the claimed sweeteners." The Examiner relies on Schwarz et al. and states that "Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33." The Examiner contends that "it would have been prima facie obvious ... to modify the compositions of Curatolo et al. such that use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose." The Examiner asserts that '[o]ne having ordinary skill in the art would have been motivated to do this to obtain the desired taste." Applicants respectfully traverse.

As noted above, amended claim 1 of the subject application is not obvious of Curatolo further in view of Tenengauzer or Li since that combination of references does not teach or suggest making or using a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. This deficiency of Curatolo in view of either Tenengauzer or Li is not overcome further in view of Schwarz.

Schwarz is directed to a monohydrate form of azithromycin and describes a composition for oral administration consisting of azithromycin monohydrate, a sweetener, a flavourant, a buffer, optionally a filler, and optionally a thickener (see page 1, lines 11-18 of Schwarz). However, Schwarz does not teach or suggest any powder for oral suspension that contains a surface tension reducing excipient, let alone a powder form containing the amount surface tension reducing excipient recited in amended claim 1. Therefore, one of skill in the art would find no teaching or suggestion in Schwarz to modify the compositions described in the combination of Curatolo further in view of Tenengauzer, or Curatolo further in view of Li, to make or use a powder form containing the amount surface tension reducing excipient recited in amended claim 1. Thus, claims 21 and 22 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of either Tenengauzer or Li, and further in view of Schwarz for at least this reason.

In view of the above, Applicants respectfully submit that claims 21 and 22 are not obvious over Curatolo in view of either Tenengauzer or Li, and further in view of Schwarz, and request that the rejection of claims 21 and 22 under 35 U.S.C § 103(a) be withdrawn.

3. **Rejection of Claims 23 and 24 under 35 U.S.C. § 103(a)**

The Examiner rejected claims 23 and 24 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,365,574 to Singer et al. ("Singer") for the reasons set forth in the office action. In particular, the Examiner concedes that Curatolo "does not explicitly teach the claimed ethanol solvate form of azithromycin." The Examiner relies on Singer and states that "Singer et al. teach using azithromycin ethanol solvate in pharmaceutical compositions because it is less hydroscopic than azithromycin monohydrate. See col. 1, lines 60-65; col. 3, line 26." The Examiner asserts that "it would have been prima facie obvious ... to modify the compositions of Curatolo et al. such that to use azithromycin ethanol solvate." The Examiner contends that "[o]ne having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Singer et al." Applicants respectfully traverse.

As noted above, amended claim 1 of the subject application is not obvious of Curatolo since that reference does not teach or suggest making or using a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. This deficiency of Curatolo is not overcome further in view of Singer.

Singer relates to an ethanolate of azithromycin and describes various compositions including powders for reconstitution (see col. 3, lines 24-27 of Singer). However, Singer does not describe or suggest a powder formulation containing a tension reducing excipient in the amount recited in amended claim 1. Therefore, one of skill in the art would find no teaching or suggestion in Singer to modify the compositions described in Curatolo to make or use a powder form containing the amount surface tension reducing excipient recited in amended claim 1. Thus, claims 23 and 24 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of Singer for at least this reason.

In view of the above, Applicants respectfully submit that claims 23 and 24 are not obvious over Curatolo in view of Singer, and request that the rejection of claims 23 and 24 under 35 U.S.C § 103(a) be withdrawn.

4. **Rejection of Claims 24 and 25 under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 24 and 25 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view Singer, and further in view of Schwarz for the reasons set forth in the office action. In particular, the Examiner concedes that "Curatolo et al. does not explicitly teach the claimed sweeteners." The Examiner relies on Schwarz and states that "Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33." The Examiner contends that "it would have been prima facie obvious ... to modify the compositions of Curatolo et al. such that to us aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose." The Examiner

asserts that "[o]ne having ordinary skill in the art would have been motivated to do this to obtain the desired taste." Applicants respectfully traverse.

As noted above, amended claim 1 of the subject application is not obvious of Curatolo in view of Singer since that combination of references does not teach or suggest making or using a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. This deficiency of Curatolo in view of Singer is not overcome further in view of Schwarz.

As discussed above, Schwarz does not teach or suggest any powder for oral suspension that contains a surface tension reducing excipient, let alone a powder form containing the amount surface tension reducing excipient recited in amended claim 1. Therefore, one of skill in the art would find no teaching or suggestion in Schwarz to modify the powder compositions described in the combination of Curatolo in view of Singer and thereby arrive at a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. Thus, claims 24 and 25 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of Singer, and further in view of Schwarz, for at least this reason.

In view of the above, Applicants respectfully submit that claims 24 and 25 are not obvious over Curatolo in view of Singer and further in view of Schwarz, and request that the rejection of claims 24 and 25 under 35 U.S.C § 103(a) be withdrawn.

5. Rejection of Claims 27 and 28 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 27 and 28 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,245,903 to Karimian et al. ("Karimian") for the reasons set forth in the office action. The Examiner concedes that Curatolo "does not explicitly teach the claimed isopropanol solvate of azithromycin." The Examiner relies on Karimian and states that "Karimian et al. teach using azithromycin isopropanol solvate in pharmaceutical compositions because it is a non-hydroscopic form of azithromycin and, therefore, is more stable than anhydrous azithromycin. See col. 2, lines 35-41; col. 3, lines 22-60." The Examiner contends that "it would have been obvious ... to modify the compositions of Curatolo et al. such that to use azithromycin isopropanol solvate." The Examiner asserts that "[o]ne having ordinary skill in the art would have been motivated to do this to obtain the improved stability of the compositions as suggested by Karimian et al. Applicants respectfully traverse.

As noted above, amended claim 1 of the subject application is not obvious over Curatolo because that reference does not teach or suggest making or using a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. This deficiency of Curatolo is not overcome further in view of Karimian.

Karimian relates to azithromycin monohydrate isopropanol clathrate. However, Karimian does not describe or suggest any powder formulation, let alone a powder formulation containing a tension reducing excipient in the amount recited in amended claim 1. Therefore, one of skill in the art would find no teaching or suggestion in Karimian to modify the compositions described in Curatolo to make or use a powder form containing the amount surface tension reducing excipient recited in

amended claim 1. Thus, claims 27 and 28 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of Karimian for at least this reason.

In view of the above, Applicants respectfully submit that claims 27 and 28 are not obvious over Curatolo in view of Karimian, and request that the rejection of claims 27 and 28 under 35 U.S.C § 103(a) be withdrawn.

6. **Rejection of Claim 11 under 35 U.S.C. § 103(a)**

The Examiner has rejected claim 11 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,383,527 to Artman et al. ("Artman") for the reasons set forth in the office action. In particular, the Examiner states that "Curatolo et al. teach various flavors as discussed previously." However, the Examiner conceded that Curatolo "does not teach the compounds claimed in the instant claim." The Examiner states that "it is well known in the art of pharmaceutical and food compositions to use isoamyl valerate of the instant claim as an FDA-accepted flavoring agent. See Artman et al. @ col. 8, lines 6-12." The Examiner contends that "it would have been prima facie obvious ... to modify the compositions of Curatolo et al. such that to use isoamyl isovalerate for its art-recognized purpose as a flavoring agent." The Examiner asserts that "[o]ne having ordinary skill in the art would have been motivated to do this to obtain the desired flavor/aroma of the composition. Applicants respectfully traverse.

As noted above, amended claim 1 of the subject application is not obvious over Curatolo because that reference does not teach or suggest making or using a powder for oral suspension containing the amount surface tension reducing excipient recited in amended claim 1. This deficiency of Curatolo is not overcome further in view of Artman.

Artman relates to combinations of valerian extract and at least on NSAID and states that isoamyl isovalerate is an acceptable flavoring agent (see col. 8, line 7 of Artman). However, Artman does not describe or suggest any powder formulation containing a tension reducing excipient in the amount recited in amended claim 1. Therefore, one of skill in the art would find no teaching or suggestion in Artman to modify the compositions described in Curatolo to make or use a powder form containing the amount surface tension reducing excipient recited in amended claim 1. Thus, claim 11 which depends directly upon amended claim 1 is not obvious over Curatolo in view of Artman for at least this reason.

In view of the above, Applicants respectfully submit that claim 11 is not obvious over Curatolo in view of Artman, and request that the rejection of claim 11 under 35 U.S.C § 103(a) be withdrawn.

In summary, none of the combinations of cited references teaches or suggests making or using a powder for oral suspension containing a non-dihydrate form of azithromycin; a form enhancer; and a form conversion enhancer which is a surface tension reducing in the amount specified in amended claim 1. Moreover, none of the combinations of cited references teaches or even suggests the unexpectedly improved properties exhibited by the formulations recited in the amended claims of the subject application. Therefore, Applicants submit that claims 11 and 20-28, all of which depend

directly or indirectly upon amended claim 1, are not obvious over any of the combinations of cited references, and request that the rejections of these claims under 35 U.S.C § 103(a) be withdrawn.

V. New Claims 79 and 80

As noted above, new claim 79 depends upon claim 9 and specifies that the azithromycin surface tension reducing excipient is anionic surfactant. New claim 80 depends upon new claim 79 and specifies that the anionic surfactant is selected from the group consisting of sodium lauryl sulfate and sodium dioctyl sulfosuccinate. New claims 79 and 80 both depend indirectly upon amended claim 1. For the reasons set forth above, none of the cited references anticipates or obviates the subject matter recited in amended claim 1. Therefore, dependent claims 79 and 80 are also not anticipated by Curatolo or Tenengauzer; and dependent claims 79 and 80 are not obvious over Curatolo in combination with any of the other cited references.

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

Date: February 4, 2008

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